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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,393	01/26/2004	Richard L. Veech	604-707	4584

23117 7590 08/20/2010

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
08/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,393	VEECH, RICHARD L.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-39* is/are rejected.

7)☒ Claim(s) *35 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/16/2010; 6/18/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicants' arguments, filed 6/18/2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's arguments, see pp. 4-7, filed 6/16/2010, with respect to the rejection(s) of claim(s) 32 and 34 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as outlined below.

The rejection is withdrawn as a result of the claim amendment excluding from the instant claims the compound on which the rejection was based, a hydroxybutyryl carnitine.

Claim Objections

3. Claims 35-36 are objected to because of the following informalities: The claims identify their status that they are "currently amended"; however, no claims with these numbers were previously presented; the claims appear to be amendments of prior claims 32-33. Applicant is advised that any new claims presented are to be designated as "new", and should not contain strike-out text or underlining. Appropriate correction is required.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e), 120 and 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. PCT/US98/05072 and US Provisional Application No. 60/040,858, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. There is no disclosure of a hydroxybutyrl carnitine, recited in instant independent claim 35 in the earliest two applications of the instant priority chain of applications. Therefore the earliest available date for the subject matter of methods that exclude a hydroxybutyryl carnitine is the filing date of Application No. 09/397,100 of 9/19/1999. The salts recited in claim 36, last line does not have description in the instant application, and is New Matter (see rejection below). Therefore, the earliest data available to claim 36 is the filing date of the instant application, 1/26/2004.

Specification

5. The disclosure is objected to because of the following informalities: The term disclosed at p. 23, line 9; i.e., "C_{1-4} alkyl esters", is difficult to read and has been interpreted by the printing department of the USPTO as "C_{14} alkyl esters" (see US 2004/0266872 A1, paragraph 0093). (C_{14} alkyl esters are inconsistent with lower alkyl esters disclosed at this location.) The same issue is present at p. 26, line 7. "Estsr" at p. 26, line 22 is misspelled.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 35-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is necessitated by the claim amendment, and the IDS filed 6/16/2010.

Claim 36 recites "free fatty acids, the metabolism of which is through β-oxidation". A review of the location identified as providing support for this limitation did not identify any specific free fatty acid with the recited metabolism property, let alone, which compound will be effective to raise the patient's blood level of ketone bodies to the recited level of claim 35. Therefore, the disclosure does not make clear which compound(s) fall within the metes and bounds of the recited phrase.

Claim 36 also recites "medium chain length triglycerides". A review of the specification indicates only that high margarine is contemplated as providing a source of these materials. It is not clear which other compounds, not in margarine, will be effective to raise the patient's blood level of ketone bodies to the recited level of claim 35.

Claim 35 recites a physiologically acceptable salt of D-β-hydroxybutyric acid or acetoacetate. However, claim 36, dependent thereon, recites "a physiologically acceptable salt of any of these" (of various classes of metabolic precursor); salts of metabolic precursors are not within the scope of claim 35, rendering all of the instant claims indefinite with respect to these salts being within or excluded by the instant claims.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The language of the last line of claim 36, "a physiologically acceptable salt of any of these" is considered New Matter, not disclosed in the specification as filed. It is noted that limited groups of compounds that are metabolic precursors are disclosed along with their salts (see original claims 11, 15, 19).

However, none of these specific groups of compounds are commensurate with any one of the classes of compounds recited in instant claim 36, and, even taken together, do not provide description of salts of all four of the broad classes of compounds recited in claim 36. Therefore, the recitation of these salts is New Matter.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 35-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Martin et al. (US 6,380,244 B2; 2002; filed 1999 Jul 22; priority 1998 Jul; cited in a prior Office Action).

12. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. (US 6,380,244 B2; 2002; cited in a prior Office Action).

This rejection is necessitated by the claim amendment.

Based on the earliest priority date accorded to instant claims 35 and 37-39 of 9/16/1999, Martin applies as prior art under 35 USC 102(e), with an earlier filing date

and an earlier priority claim. For instant claim 36, with a date of 1/24/2004. Martin applies as prior art under 35 USC 102(b).

As is present on the record, Martin teaches all of the components of the claims: increasing ketone body levels in the blood of mammals by oral administration of linear or cyclic oligomers and/or derivatives of 3-hydroxyacids, preferably 3-hydroxybutyrate, alone, or in combination with acetoacetate (abstract); D-ß-hydroxybutyrate is taught (column 3, line 21); as are free fatty acids and triglycerides (column 7, line 25); treatment of a variety of neurodegenerative diseases using these compounds, including Alzheimer's disease, vascular dementia, senile dementia of Lewis body type, dementia of Parkinsonism with frontal atrophy (an inherent component of these conditions is memory loss associated with aging) (column 8, lines 28-48); these compounds are effective, at least in part, because using elevated levels of ketone bodies can improve nerve cell function and growth (column 8, lines 28-48); amounts administered result in blood levels typically in the range of 7.5 mM (column 8, lines 28-48).

Additionally, the claimed subject matter of Martin also anticipates the instant claims: modulating blood ketone levels with compounds that include an oligomer of 3-hydroxybutyric acid (claim 1); a method of treating a neurodegenerative disorder in a mammal including linear homo-oligomers of 3-hydroxybutyric acid in combination with acetoacetate (oligomers of 3-hydroxybutyric acid are recited in instant claim 36 and read on instant claims 35-36 and 38-39; acetoacetate reads on instant claims 35-39; claim 10); following said administration the resulting blood ketone level is effective to increase the cardiac efficiency of the mammal (claim 11); neurodegenerative disorders

include Alzheimer's disease (claim 12). Definitions for increased ketone levels from the specification include the concentration of 3-hydroxybutyrate in the urine was found to be 3.5 or 1 mM for short and medium oligomers (col. 11, lines 37-39), satisfying the required patient's blood level elevation of D-beta-hydroxybutric acid and acetoacetate to a level from 0.3-20 mM, recited in instant claim 35.

13. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Veech (US 6,207,856 B1; 2001; cited in a prior Office Action).

This rejection is necessitated by the claim amendment.

As outlined previously, Veech has previously disclosed the instant invention; with all of the components of the instant claims: administration of compositions comprising ketone bodies and/or their metabolic precursors that retard or prevent brain damage in memory associated brain areas such as found in Alzheimer's and similar conditions (abstract); treatment of Alzheimer's disease and other types of dementia are taught, including impairment of recent memory leading to dementia and death (memory loss associated with aging) (column2, line 61-column 3, line 57; column 20, lines 4-13); utilizing D-ß-hydroxybutyrate and acetoacetate are taught (i.e., column 7, lines 34-40); as are oral or parenteral administration of free fatty acids or triglycerides, which increase blood ketone levels to 2 mM or 5 mM (column 9, line 67-column 10, line 65); the treatment for neurodegeneration, such as Alzheimer's and Parkonsonianism, preferably elevates blood levels of ketone bodies to 0.5-20 mM (column 20, lines 32-35).

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 6/16/2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is

(571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1628